



1651 / IFW

PATENT
ATTORNEY DOCKET NO. 50254/005002

Certificate of Mailing: Date of Deposit: October 2, 2006

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Michael Reisman

Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Toner et al.

Confirmation No.: 8260

Serial No.: 10/529,453

Art Unit: 1651

§ 371 Date December 19, 2005

Examiner: Deborah K. Ware

Customer No.: 21559

Title: MICROFLUIDIC DEVICE FOR CELL SEPARATION AND USES THEREOF

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed with the exception of U.S. patents and U.S. patent application publications. Enclosed are copies of a search report from a corresponding international application and European application.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

If there are any other charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date:

October 2, 2006

J. Cooper McDonald
Paul T. Clark

Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

J. Cooper McDonald, Ph.D.
Patent Agent
Reg. No. 52,011



SUBSTITUTE FORM PTO-1449 (MODIFIED) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
		Serial No.	10/529,453
		Applicant	Toner et al.
		§ 371 Date	December 19, 2005
		Group	1651
		IDS Filed	October 2, 2006

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
	4,508,625	Apr. 2, 1985	Graham			
	4,664,796	May 12, 1987	Graham et al.			
	4,814,098	Mar. 21, 1989	Inada et al.			
	5,153,117	Oct. 6, 1992	Simons			
	5,186,827	Feb. 16, 1993	Liberti et al.			
	5,304,487	Apr. 19, 1994	Wilding et al.			
	5,432,054	Jul. 11, 1995	Saunders et al.			
	5,447,842	Sep. 5, 1995	Simons			
	5,457,024	Oct. 10, 1995	Goldbard			
	5,466,574	Nov. 14, 1995	Liberti et al.			
	5,587,070	Dec. 24, 1996	Pall et al.			
	5,639,669	Jun. 17, 1997	Ledley			
	5,648,220	Jul. 15, 1997	Bianchi et al.			
	5,707,799	Jan. 13, 1998	Hansmann et al.			
	5,731,156	Mar. 24, 1998	Golbus			
	5,750,339	May 12, 1998	Smith			
	5,770,029	Jun. 23, 1998	Nelson et al.			
	5,866,345	Feb. 2, 1999	Wilding et al.			
	5,879,624	Mar. 9, 1999	Boehringer et al.			
	5,952,173	Sep. 14, 1999	Hansmann et al.			
	5,962,234	Oct. 5, 1999	Golbus			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/529,453
		Applicant	Toner et al.
		§ 371 Date	December 19, 2005
		Group	1651
(37 C.F.R. § 1.98(b))		IDS Filed	October 2, 2006

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
	5,993,665	Nov. 30, 1999	Terstappen et al.			
	6,013,188	Jan. 11, 2000	Terstappen et al.			
	6,036,857	Mar. 14, 2000	Chen et al.			
	6,120,856	Sep. 19, 2000	Liberti et al.			
	6,156,270	Dec. 5, 2000	Buechler			
	6,241,894	Jun. 5, 2001	Briggs et al.			
	6,291,249	Sep. 18, 2001	Mahant et al.			
	6,365,362	Apr. 2, 2002	Terstappen et al.			
	6,368,871	Apr. 9, 2002	Christel et al.			
	6,454,938	Sep. 24, 2002	Moon et al.			
	6,465,225	Oct. 15, 2002	Fuhr et al.			
	6,605,454	Aug. 12, 2003	Barenburg et al.			
	6,632,652	Oct. 14, 2003	Austin et al.			
	6,689,615	Feb. 10, 2004	Murto, et al.			
	6,746,503	June 8, 2004	Benett et al.			
	6,770,434	Aug. 3, 2004	Shvets et al.			
	6,881,315	Apr. 19, 2005	Iida et al.			
	6,911,345	Jun. 28, 2005	Quake et al.			
	6,960,449	Nov. 1, 2005	Wang et al.			
	2002/0006621	Jan. 17, 2002	Bianchi			
	2002/0012931	Jan. 31, 2002	Waldman, et al.			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
		Serial No.	10/529,453
		Applicant	Toner et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		§ 371 Date	December 19, 2005
		Group	1651
		IDS Filed	October 2, 2006
(37 C.F.R. § 1.98(b))			

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
	2002/0076825	Jun. 20, 2002	Cheng et al.			
	2003/0072682	Apr. 17, 2003	Kikinis			
	2003/0082148	May 1, 2003	Ludwig et al.			
	2004/0018116	Jan. 29, 2004	Desmond et al.			
	2004/0023222	Feb. 5, 2004	Russell et al.			
	2004/0063163	April 1, 2004	Buffiere et al.			
	2004/0072278	Apr. 15, 2004	Chou et al.			
	2004/0214240	Oct. 28, 2004	Cao			
	2004/0232074	Nov. 25, 2004	Peters et al.			
	2004/0245102	Dec. 9, 2004	Gilbert et al.			
	2005/0042685	Feb. 24, 2005	Albert et al.			
	2005/0092662	May 5, 2005	Gilbert et al.			
	2005/0118591	Jun. 2, 2005	Tamak et al.			
	2005/0123454	Jun. 9, 2005	Cox			
	2005/0124009	Jun. 9, 2005	Van Weeghel et al.			
	2005/0142663	Jun. 30, 2005	Parthasarathy et al.			
	2005/0145497	Jul. 7, 2005	Gilbert et al.			
	2005/0153342	Jul. 14, 2005	Chen			
	2005/0170418	Aug. 4, 2005	Moreland et al.			
	2005/0175505	Aug. 11, 2005	Cantor et al.			
	2005/0181463	Aug. 18, 2005	Rao et al.			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
		Serial No.	10/529,453
		Applicant	Toner et al.
		§ 371 Date	December 19, 2005
		Group	1651
		IDS Filed	October 2, 2006

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

(37 C.F.R. § 1.98(b))

U.S. PATENT DOCUMENTS						
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
	2005/0244843	Nov. 3, 2005	Chen et al.			
	2005/0272103	Dec. 8, 2005	Chen			
	2006/0008807	Jan. 12, 2006	O'Hara et al.			
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION						
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	EP0094193	Nov. 16, 1983	EPO			
	EP0637996	Feb. 15, 1995	EPO			
	EP0739240	Oct. 30, 1996	EPO			
	EP1409727	Nov. 9, 2005	EPO			
	FR2659347	Sep. 13, 1991	France			
	WO1985/02201	May 23, 1985	WIPO			
	WO1991/07660	May 30, 1991	WIPO			
	WO1997/46882	Dec. 11, 1997	WIPO			
	WO1998/10267	Mar. 12, 1998	WIPO			
	WO1998/12539	Mar. 26, 1998	WIPO			
	WO1998/22819	May 28, 1998	WIPO			
	WO2000/62931	Oct. 26, 2000	WIPO			
	WO2001/51668	Jul. 19, 2001	WIPO			
	WO2003/018757	Mar. 6, 2003	WIPO			
	WO2003/019141	Mar. 6, 2003	WIPO			
	WO2003/035894	May. 1, 2003	WIPO			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50254/005002
	Serial No.	10/529,453
	Applicant	Toner et al.
	§ 371 Date	December 19, 2005
	Group	1651
	IDS Filed	October 2, 2006

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION						
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	WO2003/071278	Aug. 28, 2003	WIPO			
	WO2003/085379	Oct. 16, 2003	WIPO			
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)						
	Adinolfi, "On a Non-Invasive Approach to Prenatal Diagnosis Based on the Detection of Fetal Nucleated Cells in Maternal Blood Samples," Prenat. Diagn. 11:799-804 (1991).					
	Adinolfi et al., "Gene Amplification to Detect Fetal Nucleated Cells in Pregnant Women," Lancet 2:328-329 (1989).					
	Al-Mufti et al., "Distribution of fetal and embryonic hemoglobins in fetal erythroblasts enriched from maternal blood," Haematologica 86:357-362 (2001).					
	Bertero et al., "Circulating 'Trophoblast' Cells in Pregnancy Have Maternal Genetic Markers," Prenat. Diagn. 8:585-590 (1988).					
	Bianchi et al., "Direct Hybridization to DNA from Small Numbers of Flow-Sorted Nucleated Newborn Cells," Cytometry 8:197-202 (1987).					
	Bianchi et al., "Isolation of Male Fetal DNA from Nucleated Erythrocytes (NRBC) in Maternal Blood," Pediatr. Res. May 1-4, 1989: 139A Abstract 818 (1989).					
	Bianchi et al., "Demonstration of Fetal Gene Sequences in Nucleated Erythrocytes Isolated from Maternal Blood," Am. J. Hum. Genet. Supplement to 45:A252 Abstract 0991 (1989).					
	Bianchi et al., "Isolation of Fetal DNA from Nucleated Erythrocytes in Maternal Blood," PNAS 87:3279-3283 (1990).					
	Bianchi et al., "Possible Effect of Gestational Age on the Detection of Fetal Nucleated Erythrocytes in Maternal Blood," Prenat. Diagn. 11:523-528 (1991).					
	Bickers et al., "Fetomaternal Transfusion Following Trauma," Obstet. Gynecol. 61:258-259 (1983).					
	Bigbee et al., "Monoclonal Antibodies Specific for the M- and N-Forms of Human Glycophorin A," Mol. Immunol. 20:1353-1362 (1983).					
	Bohmer et al., "Differential development of fetal and adult haemoglobin profiles in colony culture: isolation of fetal nucleated red cells by two-colour fluorescence labelling," British Journal of Haematology 103:351-360 (1998).					
	Brody et al., "Deformation and flow of red blood cells in a synthetic lattice: evidence for an active cytoskeleton," Biophys. J. 68:2224-2232 (1995).					
	Bulmer and Johnson, "Antigen Expression by Trophoblast Populations in the Human Placenta and Their Possible Immunobiological Relevance," Placenta 6:127-140 (1985).					
	Cai et al., "A New TATA Box Mutation Detected at Prenatal Diagnosis for β -Thalassemia," Am. J. Hum. Genet. 45:112-114 (1989).					
	Cai et al., "Rapid Prenatal Diagnosis of β Thalassemia Using DNA Amplification and Nonradioactive Probes," Blood 73:372-374 (1989).					
	Carlson et al., "Self-Sorting of White Blood Cells in a Lattice," Physical Review Letters 79:2149-2152 (1997).					
	Chang et al. Biomimetic technique for adhesion-based collection and separation of cells in a microfluidic channel. Lab Chip. 5:64-73 (2005).					

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
		Serial No.	10/529,453
		Applicant	Toner et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		§ 371 Date	December 19, 2005
		Group	1651
		IDS Filed	October 2, 2006
(37 C.F.R. § 1.98(b))			

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Choolani et al., "Characterization of first trimester fetal erythroblasts for non-invasive prenatal diagnosis," Molecular Human Reproduction 9:227-235 (2003).
	Chou et al., A Microfabricated Device for Sizing and Sorting DNA Molecules. PNAS 96:11-13 (1999).
	Christensen et al., "Fetal Cells in Maternal Blood: A Comparison of Methods for Cell Isolation and Identification," Fetal Diagnosis and Therapy 20:106-112 (2005).
	Chueh and Golbus, "Prenatal Diagnosis Using Fetal Cells in the Maternal Circulation," Semin. Perinatol. 14:471-482 (1990).
	Chueh and Golbus, "Prenatal Diagnosis Using Fetal Cells in the Maternal Circulation," West. J. Med. 159:308-311 (1993).
	Chueh and Golbus, "The Search for Fetal Cells in the Maternal Circulation," J. Perinatol. Med. 19:411-420 (1991).
	Clayton et al., "Fetal Erythrocytes in the Maternal Circulation of Pregnant Women," Obstetr. Gynecol. 23:915-919 (1964).
	Cohen and Zuelzer, "Mechanisms of Isoimmunization II. Transplacental Passage and Postnatal Survival of Fetal Erythrocytes in Heterospecific Pregnancies," Blood 30:796-804 (1967).
	Covone et al., "Trophoblast Cells in Peripheral Blood from Pregnant Women," Lancet 2:841-843 (1984).
	Covone et al., "Analysis of Peripheral Maternal Blood Samples for the Presence of Placenta-Derived Cells Using Y-Specific Probes and McAb H315," Prenat. Diagn. 8:591-607 (1988).
	Das et al., "Dielectrophoretic segregation of different human cell types on microscope slides." Anal. Chem. 77:2708-2719 (2005).
	Douglas et al., "Trophoblast in the Circulating Blood During Pregnancy," Am. J. Obstet. Gynecol. 78:960-973 (1959).
	Elias, "Prenatal Blood Test Can Signal Genetic Disorders," The Boston Globe. Oct. 8, 1991:4.
	Hennerbichler et al., "Detection and relocation of cord blood nucleated red blood cells by laser scanning cytometry," Cytometry 48:87-92 (2002).
	Hviid, "In-Cell PCR Method for Specific Genotyping of Genomic DNA from One Individual in a Mixture of Cells from Two Individuals: A Model Study with Specific Relevance to Prenatal Diagnosis Based on Fetal Cells in Maternal Blood," Clin. Chem. 48:2115-23 (2002).
	Jan and Herzenberg, "Fetal Erythrocytes Detected and Separated from Maternal Blood by Electronic Fluorescent Cell Sorter," Texas Rep. Biol. Med. 31:575 (1973).
	Kelly, "A Simpler, Safer Blood Test for Birth Defects," USA Today. Nov. 14, 1989:1D.
	de Kretser et al., The Separation of Cell Populations using Monoclonal Antibodies attached to Sepharose. Tissue Antigens 16:317-325 (1980).
	Krivacic et al., "A rare-cell detector for cancer." PNAS 101:10501-10504 (2004).
	Kulozik and Pawlowitzki, "Fetal Cell in the Maternal Circulation: Detection by Direct AFP-Immunofluorescence," Hum. Genet. 62:221-224 (1982).
	Lloyd et al., "Intrapartum Fetomaternal Bleeding in Rh-Negative Women," Obstet. Gynecol. 56:285-287 (1980).
	Melville et al., "Direct magnetic separation of red cells from whole blood," Nature 255:706 (1975).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50254/005002
		Serial No.	10/529,453
		Applicant	Toner et al.
		§ 371 Date	December 19, 2005
		Group	1651
		IDS Filed	October 2, 2006
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			
(37 C.F.R. § 1.98(b))			

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Parano et al., "Noninvasive Prenatal Diagnosis of Chromosomal Aneuploidies by Isolation and Analysis of Fetal Cells from Maternal Blood," Am. J. Med. Genet. 101:262-267 (2001).
	Price et al., "Prenatal diagnosis with fetal cells isolated from maternal blood by multiparameter flow cytometry," Am J Obstet Gynecol. 165:1731-1737 (1991).
	Raeburn, "Fetal Blood Cells Found in Pregnant Women's Blood," Associated Press. July 28, 1989.
	Rolle, et al., Increase in number of circulating disseminated epithelial cells after surgery for non-small cell lung cancer monitored by MAINTRAC is a predictor for relapse: a preliminary report. World Journal of Surgical Oncology. 3:18 (2005).
	Saltus, "New Test Speeds Detection of Birth Defects," The Boston Globe. Oct. 8, 1991:4.
	Saltus, "Noninvasive Way Is Cited to Detect Down Syndrome in Fetuses," The Boston Globe. Nov. 12, 1992:8.
	Schröder, "Transplacental Passage of Blood Cells," J. Med. Genet. 12:230-242 (1975).
	Schröder and de la Chapelle, "Fetal Lymphocytes in the Maternal Blood," Blood 39:153-162 (1972).
	Sitar et al., "The use of non-physiological conditions to isolate fetal cells from maternal blood," Exp Cell Res. 302:153-161 (2005).
	Snider, "Birth Defects Detected with Simple Blood Test," USA Today. Oct. 9, 1991.
	Sohda et al., "The Proportion of Fetal Nucleated Red Blood Cells in Maternal Blood: Estimation by FACS Analysis," Prenatal Diagnosis 17:743-752 (1997).
	Stipp, "IG Labs Licenses New Technology for Fetal Testing," The Wall Street Journal. Aug. 10, 1990:B5.
	Takayasu et al., "Continuous Magnetic Separation of Blood Components from Whole Blood," : IEEE Trans. On Applied Superconductivity. 10:927-930 (2000).
	Toner et al., "Blood-on-a-Chip," Annual Review of Biomedical Engineering. 7:77-103 (2005).
	UPI, "Researchers find safer prenatal tests," The Boston Herald. Nov. 14, 1989:25.
	Walknowska et al., "Practical and Theoretical Implications of Fetal/Maternal Lymphocyte Transfer," Lancet 1:1119-1122 (1969).
	Zborowski et al., "Red Blood Cell Magnetophoresis," Biophysical Journal 84:2638-2645 (2003).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	